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FORM PTO-1390 (REV. 11-2000)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTORNEY'S DOCKET NUMBER MAG 2 0003	
TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371				U.S. APPLICATION NO. (If known, see 37 CFR 1.5 10/070062	
INTERNATIONAL APPLICATION NO. PCT/GB00/03364		INTERNATIONAL FILING DATE 31 August 2000 (31.08.00)		PRIORITY DATE CLAIMED 31 August 1999 (31.08.99) 30 November 1999 (30.11.99)	
TITLE OF INVENTION METAL-CONTAINING COMPOSITIONS, PREPARATIONS AND USES					
APPLICANT(S) FOR DO/EO/US HICKOK, Stephen, Spaulding					
Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:					
<ol style="list-style-type: none"> 1. <input checked="" type="checkbox"/> This is a FIRST submission of items concerning a filing under 35 U.S.C. 371. 2. <input type="checkbox"/> This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 U.S.C. 371. 3. <input type="checkbox"/> This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below. 4. <input type="checkbox"/> The US has been elected by the expiration of 19 months from the priority date (Article 31). 5. <input checked="" type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371(c)(2)) <ol style="list-style-type: none"> a. <input type="checkbox"/> is attached hereto (required only if not communicated by the International Bureau). b. <input checked="" type="checkbox"/> has been communicated by the International Bureau. c. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US). 6. <input type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)). <ol style="list-style-type: none"> a. <input type="checkbox"/> is attached hereto. b. <input type="checkbox"/> has been previously submitted under 35 U.S.C. 154(d)(4). 7. <input checked="" type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)) <ol style="list-style-type: none"> a. <input type="checkbox"/> are attached hereto (required only if not communicated by the International Bureau). b. <input type="checkbox"/> have been communicated by the International Bureau. c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired. d. <input checked="" type="checkbox"/> have not been made and will not be made. 8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)). 9. <input checked="" type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). 10. <input type="checkbox"/> An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)). 					
Items 11 to 20 below concern document(s) or information included:					
<ol style="list-style-type: none"> 11. <input type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98. 12. <input checked="" type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included. 13. <input checked="" type="checkbox"/> A FIRST preliminary amendment. 14. <input type="checkbox"/> A SECOND or SUBSEQUENT preliminary amendment. 15. <input type="checkbox"/> A substitute specification. 16. <input type="checkbox"/> A change of power of attorney and/or address letter. 17. <input type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821 - 1.825. 18. <input type="checkbox"/> A second copy of the published international application under 35 U.S.C. 154(d)(4). 19. <input type="checkbox"/> A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4). 20. <input checked="" type="checkbox"/> Other items or information: <ol style="list-style-type: none"> 1) Copy of International Publication No. WO 01/15554 2) Copy of International Preliminary Examination Report 3) Statement of Status as a Small Business Entity 					

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF : Stephen Spaulding Hickok
FOR : METAL-CONTAINING
COMPOSITIONS, PREPARATIONS
AND USES
INTERNATIONAL
APPLICATION NO. : PCT/GB00/03364
INTERNATIONAL
FILING DATE : 31 August 2000
ATTORNEY DOCKET NO. : MAG 2 0003

Cleveland, Ohio 44114-2518
February 27, 2002

PRELIMINARY AMENDMENT

Assistant Commissioner for Patents
Washington, DC 20231

Dear Sir:

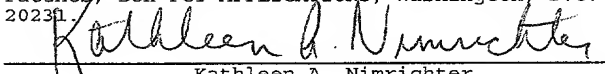
Prior to examination of the above-captioned patent
application, please amend the application as follows:

IN THE CLAIMS:

Please amend claims 3 - 5, 7, 9, 10, 12, 14, 15, 17,
21 - 33 as follows:

3. (Amended) A composition as claimed in claim 1
which essentially consists of (i) - (iv) as defined in
claim 1.

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20231.


Kathleen A. Nimrichter

4. (Amended) A composition as claimed in claim 1 which consists of (i) - (iv) as defined in claim 1 apart from any unavoidable impurities.

5. (Amended) A composition as claimed in claim 1 wherein (i) is an inorganic salt of zinc, magnesium, copper, selenium, iron, nickel, titanium or vanadium.

7. (Amended) A composition as claimed in claim 5 in which said salt (i) is a zinc, magnesium, copper, iron or selenium salt.

9. (Amended) A composition as claimed in claim 1 in which the metal ion modifier (ii) is at least one metal ion binding, complexing, or sequestering agent.

10. (Amended) A composition as claimed in claim 1 wherein (ii) comprises one or more inorganic ammonium compounds capable of dissociating in water into ammonium ions such as one or more of: ammonium sulphate, ammonium chloride, ammonium phosphate, and ammonium citrate.

12. (Amended) A composition as claimed in claim 1 in which (iii) comprises one or more of sulphuric, hydrochloric, phosphoric and citric acids.

14. (Amended) A composition as claimed in claim 1 in which (iv) consists essentially of distilled water or

entirely of distilled water apart from any unavoidable impurities.

15. (Amended) A composition as claimed in claim 1 in which the pH value is less than 5, preferably less than 4, more preferably less than 3, most preferably less than 2.5.

16. (Amended) A composition as claimed in claim 15 in which the pH value is 2 or less such as in the range of 1 to 2.

17. (Amended) A composition as claimed in claim 1 in which the electrolytic potential is in excess of 20 millivolts, preferably in excess of 50 millivolts and more preferably in excess of 100 millivolts.

21. (Amended) A method of making a composition as claimed in claim 1 comprising dissolving (i) in distilled water, adding (ii) and mixing or allowing to dissolve.

22. (Amended) A method as claimed in claim 21 in which (i) is as defined in claim 5.

23. (Amended) A method as claimed in claim 21 in which (ii) is defined in claim 11.

24. (Amended) A method as claimed in claim 21

wherein (iii) is as defined in claim 12.

25. (Amended) Use of a composition as claimed in claim 1 as a medicament for treating or preventing a pathogenic disease or disorder.

26. (Amended) A composition as claimed in claim 1 for the preparation of a medicament for treating or preventing a pathogenic disease or disorder.

27. (Amended) Use of a composition as claimed in claim 1 as an antimicrobial, antiviral, anti-retrovirus, or antifungal formulation.

28. (Amended) An antimicrobial, antiviral, antiretrovirus or antifungal formulation comprising a composition as claimed in claim 1 in conjunction with a pharmaceutically acceptable carrier, diluent or excipient therefor.

29. (Amended) Use of a composition as claimed in claim 1 for the treatment of water, or predominantly water-containing material.

30. (Amended) Use of a composition as claimed in claim 1 for the treatment of sewage, industrial or municipal wastes.

31. (Amended) Use of a composition as claimed in claim 1 for the treatment of foodstuffs as a disinfectant or bactericide, particularly copper containing such compositions.

32. (Amended) Use of a composition as claimed in claim 1 for the preservation of plants, flowers, trees or shrubs.

33. (Amended) Use of a composition as claimed in claim 1 in the treatment of a metal for coating, sealing, plating or otherwise forming an anti-corrosive layer upon a metallic substrate.

REMARKS

This application is the entry into the national phase in the United States concerning International Application PCT/GB00/03364. In the International Application, there are a number of multiply dependent claims. Some of these claims are themselves dependent from other multiply dependent claims. Since such a claim structure is impermissible in the United States, applicant takes this opportunity to remove all multiple dependencies from the claims.

Prompt and favorable examination of claims 1-34 is respectfully requested.

Respectfully submitted,

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EXHIBIT A

Version with Markings to Show Changes Made

IN THE CLAIMS:

Please amend claims 3 - 5, 7, 9, 10, 12, 14, 15, 17, 21 - 33 as follows:

3. (Amended) A composition as claimed in claim 1 [or 2] which essentially consists of (i) - (iv) as defined in claim 1.

4. (Amended) A composition as claimed in [any preceding] claim 1 which consists of (i) - (iv) as defined in claim 1 apart from any unavoidable impurities.

5. (Amended) A composition as claimed in [any preceding] claim 1 wherein (i) is an inorganic salt of zinc, magnesium, copper, selenium, iron, nickel, titanium or vanadium.

7. (Amended) A composition as claimed in claim 5 [or 6] in which said salt (i) is a zinc, magnesium, copper, iron or selenium salt.

9. (Amended) A composition as claimed in [any preceding] claim 1 in which the metal ion modifier (ii) is at least one metal ion binding, complexing, or sequestering agent.

10. (Amended) A composition as claimed in [any preceding] claim 1 wherein (ii) comprises one or more inorganic ammonium compounds capable of dissociating in water into ammonium ions such as one or more of: ammonium sulphate, ammonium chloride, ammonium phosphate, and ammonium citrate.

12. (Amended) A composition as claimed in [any preceding] claim 1 in which (iii) comprises one or more of sulphuric, hydrochloric, phosphoric and citric acids.

14. (Amended) A composition as claimed in [any preceding] claim 1 in which (iv) consists essentially of distilled water or entirely of distilled water apart from any unavoidable impurities.

15. (Amended) A composition as claimed in [any preceding] claim 1 in which the pH value is less than 5, preferably less than 4, more preferably less than 3, most preferably less than 2.5.

17. (Amended) A composition as claimed in [any preceding] claim 1 in which the electrolytic potential is in excess of 20 millivolts, preferably in excess of 50 millivolts and more preferably in excess of 100 millivolts.

21. (Amended) A method of making a composition as

claimed in [any preceding] claim 1 comprising dissolving (i) in distilled water, adding (ii) and mixing or allowing to dissolve.

22. (Amended) A method as claimed in claim 21 in which (i) is as defined in [any one of claims 5 to 8] claim 5.

23. (Amended) A method as claimed in claim 21 [or 22] in which (ii) is defined in [any one of claims 9 to 11] claim 11.

24. (Amended) A method as claimed in [any one of claims 1 to 21] claim 21 wherein (iii) is as defined in claim 12 [or 13].

25. (Amended) Use of a composition as claimed in [any one of claims 1 to 21] claim 1 as a medicament for treating or preventing a pathogenic disease or disorder.

26. (Amended) A composition as claimed in [any one of claims 1 to 21] claim 1 for the preparation of a medicament for treating or preventing a pathogenic disease or disorder.

27. (Amended) Use of a composition as claimed in [any one of claims 1 to 21] claim 1 as an antimicrobial, antiviral, anti-retrovirus, or antifungal formulation.

28. (Amended) An antimicrobial, antiviral, antiretrovirus or antifungal formulation comprising a composition as claimed in [any one of claims 1 to 21] claim 1 in conjunction with a pharmaceutically acceptable carrier, diluent or excipient therefor.

29. (Amended) Use of a composition as claimed in [any one of claims 1 to 21] claim 1 for the treatment of water, or predominantly water-containing material.

30. (Amended) Use of a composition as claimed in [any one of claims 1 to 21] claim 1 for the treatment of sewage, industrial or municipal wastes.

31. (Amended) Use of a composition as claimed in [any one of claims 1 to 21] claim 1 for the treatment of foodstuffs as a disinfectant or bactericide, particularly copper containing such compositions.

32. (Amended) Use of a composition as claimed in [any one of claims 1 to 21] claim 1 for the preservation of plants, flowers, trees or shrubs.

33. (Amended) Use of a composition as claimed in [any one of claims 1 to 21] claim 1 in the treatment of a metal for coating, sealing, plating or otherwise forming an anti-corrosive layer upon a metallic substrate.

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WO 01/15554

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"Metal-containing Compositions, Preparations and Uses"

It is well established that minerals i.e. traces of selected metal elements are required as part of the human diet for good health. Mineral deficiencies can lead to poor health and specific disorders. Amongst the minerals that the body requires, there are,
5 for example, the metals zinc, magnesium, copper, iron, and selenium. The human body requires traces of such minerals in soluble form whereby the corresponding metallic ions are bio-available within the bloodstream.

With the increase in highly processed and convenience foods, there are concerns that the typical diet in today's conditions may not contain sufficient vitamins and/or
10 minerals. Accordingly vitamin and mineral supplements are widely available without prescription on the basis that they are foodstuff components and not medicaments.

This invention is particularly concerned with mineral metal compositions, their preparation and uses within a mineral 'delivery' system for humans or animals. It is known that mineral salts by themselves, e.g. zinc sulphate, iron sulphate and the like will
15 dissociate in aqueous solution to form the corresponding ions e.g. Zn^{2+} and Fe^{2+} with SO_4^{2-} . However, it has been observed that the metallic mineral ions in solution within the bloodstream are not readily bio-available in the sense of being available for uptake by cells. Accordingly there are at least two mineral 'binder' systems available for enhancing bio-availability of these ions. Most mineral supplement compositions presently available
20 are based upon an inorganic chelate binder system. In such compositions, the required mineral element e.g. zinc, magnesium or the like is chemically bonded to a chelate such that bio-availability of the mineral ions is still significantly impaired. The digestive system has difficulty in leaching the mineral element away from the chelate binder for cellular uptake. This limits their bio-availability. Chelate based mineral supplements apparently
25 limit the body's absorption of the elemental mineral to some 7 to 10% of that presented. It is suggested that the remaining mineral content is not absorbed into the bloodstream, but is passed in the urine or faeces. Chelate-bound iron mineral supplements, in

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particular, can cause constipation as the chelate can act as a flocculent in the large intestine. It is desirable that such disadvantage be overcome in an alternative mineral 'delivery' system with improved bio-availability of the mineral elements.

Another mineral supplement composition is based upon a mineral salt combined
5 with an organic glutamate binder. One product based upon the glutamate bound mineral delivery system is a lozenge containing zinc for oral ingestion. However, not only does the glutamate delivery system demonstrate restricted mineral element/ion bio-availability in similar fashion to the chelates described above, but also zinc glutamate lozenges in particular tend to leave undesirable coloured stains in the mouth. Accordingly it is also
10 desirable to overcome this particular disadvantage in an alternative mineral delivery system providing better mineral element bio-availability.

In consequence it can be summarised that the existing chelate and glutamate bound mineral compositions deliver such mineral elements into the bloodstream but only a small proportion of the total content of the respective mineral element, and over a
15 relatively lengthy period of time whereby specific mineral bio-availability is limited.

The present inventor has considered the existing mineral delivery systems such as the chelate and glutamate delivery systems and their disadvantages. The present invention provides inter alia, alternative mineral delivery systems based on quite different components which have been found to improve specific mineral bio-availability in terms
20 of not only bloodstream quantities but also bloodstream absorption time.

The present inventor provides several aspects to his invention, based upon mineral or other metallic element – containing compositions, methods for preparing such compositions and uses of such compositions which encompass several distinct technical fields apart from the field of mineral supplements for the human or animal diet, namely
25 uses of the compositions for medical conditions in the treatment of a disease or disorder, treating or purifying water or sewage, use as an algacide, fungicide and disinfectant and uses in treating metal substrates to control corrosion.

Accordingly in a first aspect of this invention there is provided a metal-containing composition substantially comprising:

- (i) at least one water soluble metal compound which forms metal ions when dissolved in water,
- 5 (ii) at least one metal ion modifier as herein defined,
- (iii) at least one acid, and
- (iv) water

said composition having a pH of less than 6 and an electrolytic potential in excess of 10 millivolts.

- 10 The term 'metal' is used herein to encompass semi-metals of a mineral nature, e.g. selenium.

Such compositions preferably essentially consist of the aforesaid components with any preferred additives and more preferably consist of such ingredients, optional additives and the balance being any inevitable impurities.

- 15 In a second aspect of this invention there is provided a method of making a composition as defined in the first aspect comprising dissolving (i) in distilled water, adding (ii) and mixing or allowing to dissolve, then adding (iii) whilst simultaneously monitoring the pH and electrolytic potential of the composition until a required value of each measurement is obtained.

- 20 A third aspect of this invention provides the use of a composition as defined in the first aspect in medicine, for example the use of such a composition for preventing or treating one or more of the following pathogenic disorders, namely bacterial, fungal or viral infection, retroviral infection such as AIDS or Hepatitis C, particularly including copper containing such compositions for treating one or more of the following diseases.
- 25 namely cholera, salmonella, shigella, E.Coli and chlamydia.

A fourth aspect of this invention provides the use of a composition as defined in the first aspect, in the preparation of a medicament for use in the treatment of a disease or disorder, such as one or more of the aforementioned diseases or disorders.

The invention also provides in a fifth aspect the use of a composition as defined in
5 the first aspect in the treatment of water or water containing materials or sewage, effluent, commercial, domestic waste products as a bactericide, or algacide, flocculent viricide and/or fungicide.

A sixth aspect of the present invention provides the use of a composition as defined in the first aspect to form a corrosion resistant coating or plating for metal
10 substrates, to act as a sealant against metal corrosion.

In a seventh aspect the present invention provides the use of a composition as defined in the first aspect as a bactericidal and/or fungicidal preservative against the bacterial or fungal deterioration of edible foodstuffs.

The metal ion modifier is preferably a binder other than chelate or glutamate
15 effective to transport ions incorporating the metallic mineral element through the digestive system and into the bloodstream in bioavailable form. Such binder can be, for example, a complexing, buffering or sequestering agent. It is most preferred to use soluble ammonium compounds, such as one or more of the following ammonium salts: ammonium chloride, sulphate or phosphate.

20 Such metal ion modifiers appear particularly effective in retaining and sustaining electrolytic potential.

The present invention is based on the inventor's discoveries that an improved metallic mineral delivery system for the human or animal bloodstream and other uses
25 can be formulated from selected metal-containing electrolytes in acidic aqueous media which demonstrate a measurable electrolytic potential which is stable for a significant period of time. Such compositions have surprisingly been found, inter alia, when

ingested or absorbed to make the mineral ions more rapidly available to the body for cellular uptake, and more efficiently and sustainably in terms of percentage by weight of bio-available mineral within the bloodstream, after a given time. Additionally it would appear that the ions incorporating the metallic mineral element are more bio-active due to enhanced beneficial effects which have been observed. The ions incorporating the metallic mineral element appear to be polarised, with an overall cationic charge. Accordingly, within the present compositions, the metallic element effects appear to be synergistically improved by the metal ion modifier. In particular this appears to be the case with zinc and magnesium compositions.

10 In preferred embodiments of the invention, the metal compositions are mineral metal such compositions and can act transdermally by passing through the skin, mucosa or other mucous membrane, for even more rapid absorption into the bloodstream.

Preferred embodiments of the compositions for dietary supplement or medical uses can provide up to 90% by weight of the mineral element absorbed into the bloodstream, in bio-available and potentially more bio-active form in up to 10 minutes e.g. within 6 to 10 minutes. Accordingly such compositions for dietary or medical uses in the form of acidic aqueous electrolyte solutions can provide for rapid mineral element ion delivery to the body for cellular uptake, with less wastage of the desirable mineral passing in the urine and/or faeces.

20 In the case of preferred compositions which contain iron or zinc as the mineral element, it is possible to avoid the disadvantages of chelated iron and zinc glutamate mentioned above, whilst simultaneously providing more of these mineral elements available in the bloodstream in less time and again apparently in a more bio-active form.

The present compositions for human or animal dietary or medical use are preferably based upon the presence of at least one water soluble metal compound such as a mineral metal salt in aqueous compositions which further contain components as

defined in the first aspect and all of which said components have been designated GRAS (generally regarded as safe) food additives or other chemicals by the US-FDA

In order to make the present compositions for human or animal dietary or medical use, it is preferred for the following general preparative procedure to be adopted:

5 General Procedure

(a) The required metal such as a mineral element e.g. zinc is included by way of a soluble salt of the metal such as zinc sulphate. This is to be completely dissolved in distilled water (in contrast to deionised water) preferably 1 litre by mixing the salt into the water at ordinary room temperature, e.g. about 20°C by vigorous stirring. The
10 corresponding metallic mineral ions thereby form in the aqueous solution.

(b) When all the metallic salt has been completely dissolved in the distilled water, at least one metal ion modifier is added, preferably a sequestering, buffering or complexing agent such as one or more soluble ammonium salts, for example one or more of: ammonium sulphate, ammonium chloride, ammonium citrate, and ammonium
15 phosphate, which is mixed into the solution to dissolve therein.

(c) To the aqueous mixture, obtained in step (b), at least one acid component (e.g. sulphuric and/or citric acid or hydrochloric acid) is added carefully and slowly, preferably by measured metering, to lower the pH of the mixture to a preferred level and to simultaneously exhibit a measurable electrolytic potential until a preferred level thereof is
20 also reached. The value of electrolytic potential is preferably measured and monitored by milli-voltmeter. Several commercially available instantaneous readout pH meters can function as a milli-voltmeter by simple adjustment. Sufficient acid should be added so as to control the values of pH and electrolytic potential. This process for making the aqueous metal-containing compositions, particularly mineral metal such compositions for
25 dietary or medical use, can be likened to a form of electrometric titration.

The inventor has observed that in many embodiments, after completion of step (c) - the addition of one or more appropriate acids, most preferably GRAS designated acids.

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the compositions exhibit behaviour associated with dynamic equilibrium solutions at relatively high electrolytic potential. An exothermic reaction during step (c) may be observed. The aqueous compositions in many embodiments also appear to demonstrate the characteristics of an overall cationic solution in which positively charged cations including the metallic element outnumber the anions. Furthermore such cations when present in the bloodstream appear to be attracted to and thereby damage or destroy pathogenic cells having an overall negative charge, such as bacterial, fungal or viral cells.

In order that the invention in all its aspects may be further elucidated a plurality of non-limiting examples are now presented in tabular form for a more complete appreciation of the invention, and to enable these and other embodiments of the invention to be reduced to practice by one of ordinary skill in the art. The preparative procedure in each example corresponds to the general procedure already outlined above, using 1 litre of distilled water, or 860mls in the case of example 13a.

For the medical fields of application, the formulations can be administered orally in the range of 1 drop to 15 drops, dissolved in more water, once, twice or three times daily, depending upon the severity of the condition.

For the non-medical fields of application, the quantities to be used can be varied according to economics, effects desired, volume of material (eg water) to be treated.

The precise amounts are rather less critical and adjustments can be made by the user.

It will be appreciated that where the metal compound is a sulphate, then the metal ion modifier is preferably also a sulphate and the acid preferably is sulphuric.

Similarly where the metal compound is a chloride, the ion modifier is preferably also a chloride and the acid is preferably hydrochloric. Where the metal ion modifier is a phosphate, it is preferred to use phosphoric acid as the acid, whatever metal salt is used as the source of metallic ions.

Example No.	Mineral or other Metal Element(s) in Composition	Compound(s) / Amount	Metal ion Modifier(s) / Amount	Acid(s) / Amount	Optional Additive(s)	Final pH	Final Electrolytic Potential Millivolts (mV)	Field(s) of Application
1	Copper	Copper Sulphate 150g	Ammonium Sulphate 75g	Sulphuric 98% 37.5 mls	-	< 1.5	350-380	Medical, Anti-bacterial especially against Helicobacter Pylori
2	Copper	Copper Sulphate 150g	Ammonium Sulphate 75g	Sulphuric 98% variable*	-	1-2	> 300	Medical, anti mycological Treatment
3	Copper	Copper Sulphate 150g	Ammonium Sulphate 75g	Sulphuric 98% variable	-	< 2	> 350	Medical arthritis Alleviation
4	Copper	Copper Sulphate 200g	Ammonium Sulphate 75g	Sulphuric 98% variable	-	1-5	> 350	Substantial copper dietary supplement
5	Magnesium	Magnesium Sulphate/ 150g	Ammonium Sulphate 75g	Sulphuric 98% variable	Vitamin B1 Vitamin B3	1-2	> 350	Medical, antiviral
6	Magnesium	Magnesium Sulphate/ 150g	Ammonium Sulphate 75g	Sulphuric 98% variable	-	1-2	> 350	Medical asthma treatment or prevention
7	Magnesium	Magnesium Sulphate/ 150g	Ammonium Sulphate 75g	Sulphuric 98% variable	-	1-2	> 350	Medical, stroke treatment and prophylactic
8	Magnesium	Magnesium Sulphate/ 150g	Ammonium Sulphate 75g	Sulphuric 98% variable	Malic acid	1-2	> 350	Medical, treatment for Chronic fatigue syndrome
9	Magnesium	Magnesium Sulphate/ 100g	Ammonium Phosphate 60g	Phosphoric Acid Concentrated 40mls	Malic acid 40g	1-2	> 350	As for example 8 and also for combatting side effects in patients with retroviral disease such as AIDS and/or Hepatitis C
10	Magnesium	Magnesium Sulphate/ 150g	Ammonium Sulphate 75g	Sulphuric 98% variable	Natural Diuretic	1-2	> 350	Medical relief of pre-menstrual tension

SUBSTITUTE SHEET (RULE 26)

11	Magnesium	Magnesium Sulphate/ 150g	Ammonium Sulphate 75g	Sulphuric 98% variable	Melatonin Valerian	1-2	> 350	Medical treatment of insomnia
12	Magnesium	Magnesium Sulphate 200g	Ammonium Sulphate 75g	Sulphuric 98% variable	-	1-2	> 350	Substantial magnesium dietary supplement
13	Selenium	Selenium Sulphate 150g	Ammonium Sulphate 75g	Sulphuric 98% variable	-	1-2	> 350	Medical treatment of cancer
13a	Selenium	Selenic Acid H ₂ O ₂ Se 50g	Ammonium Phosphate 80g	Phosphoric Acid Concentrated 40 mls	-	1-2	> 350	Composition for use in the treatment of cancer, Hepatitis C and AIDS. Topical formulation of this composition has indications for treatment of melanoma
14	Iron	Iron Sulphate 200g	Ammonium Sulphate 75g	Sulphuric 98% variable	-	1-2	> 350	Substantial iron dietary supplement
15	Zinc	Zinc Sulphate 150g	Ammonium Sulphate 75g	Sulphuric 98% variable	Vitamin C	1-2	> 350	Medical, antiviral, particularly anti-retroviral eg Aids & Hepatitis C
16	Zinc	Zinc Sulphate 200g	Ammonium Sulphate 75g	Sulphuric 98% variable	Stimulants - caffeine, Nicotine and ginseng	1-2	> 350	Medical, alertness enhancer, potential hangover remedy
17	Zinc	Zinc Sulphate 150g	Ammonium Sulphate 75g	Sulphuric 98% variable	-	1-2	> 350	Substantial zinc dietary supplement

SUBSTITUTE SHEET (RULE 26)

18	Zinc	Zinc Sulphate 200g	Ammonium Sulphate 75g	Sulphuric 98% Variable	Vitamin B5 Vitamin B6 To accelerate Zinc Delivery	1-2	> 350	Medical - to counter side effects of chemotherapy
18a	Zinc	Zinc Sulphate 100g	Ammonium Sulphate 65g	Phosphoric acid concentrated 40mls	Citric acid 30g (catalyst) and pyruvic acid 50g (co-enzyme)	1-2	> 350	Same as example 43 a more preferred formulation, suitable for AIDS patients with mitochondrial dysfunction or otherwise damaged by reverse transcriptase inhibitors
19	Copper	Copper Sulphate 150g	Ammonium Phosphate 75g	Phosphoric Acid Variable	-	1-2	> 350	Fungicide, soil sterilant to replace methyl bromide, transdermal fungicide
20	Copper	Copper Sulphate 150g	Ammonium Chloride 75g	Hydrochloric acid-concentrated variable	-	1-2	> 350	As example 1
21	Copper	Copper Sulphate 150g	Ammonium Chloride 75g	Hydrochloric acid-concentrated variable	-	1-2	> 350	As example 3
22	Copper	Copper Sulphate 150g	Ammonium Chloride 75g	Hydrochloric Acid-concentrated variable	-	1-2	> 350	Medical, fungicide, oral and/or topical formulations
23	Zinc	Zinc Sulphate 150g	Ammonium Chloride 75g	Hydrochloric Acid-concentrated variable	-	1-2	> 350	Medical, antiviral
24	Copper	Copper Sulphate 200g	Ammonium Sulphate 75g	Sulphuric acid 98% variable	-	1-2	> 350	Water purification - disinfectant
25	Copper	Copper Sulphate 200g	Ammonium Sulphate 75g	Sulphuric acid 98% variable	-	1-2	> 350	Water treatment - algacide
26	Copper	Copper Sulphate 200g	Ammonium Sulphate 75g	Sulphuric Acid 98% Variable	-	1-2	> 350	Water treatment - swimming pool disinfectant

SUBSTITUTE SHEET (RULE 26)

27	Copper	Copper Sulphate 200g	Ammonium Sulphate 75g	Sulphuric Acid 98% Variable	-	1-2	> 350	Sewage treatment - disinfectant
28	Iron	Iron Sulphate 150g	Ammonium Sulphate 75g	Sulphuric Acid 98% Variable	-	1-2	> 350	Water treatment - flocculant
28a	Iron	Iron II Sulphate monohydrate 133.33g (FeSO ₄ ·H ₂ O) Molecular weight=151.91 Fe content per mole = 55.85 Fe content = 16.76% by weight	Ammonium Sulphate 66.66g	Sulphuric acid concentrated 99% 33.33mls	-	0.79	391	Water treatment, flocculant, removal of organic matter
28b	Iron	Iron II Sulphate Heptahydrate 200g FeSO ₄ ·7H ₂ O Molecular weight = 278.01 Fe content = 20.08% by weight	Ammonium Sulphate 100g	Sulphuric acid concentrated 99% 50mls	-	0.17	385	As example 28a
28c	Iron	Iron III Sulphate monohydrate 200g Fe ₂ (SO ₄) ₃	Ammonium Sulphate 100g	Sulphuric acid concentrated 99% 50mls	-	0.15	404	As example 28a
28d	Iron	Iron III Chloride 200g FeCl ₃	Ammonium chloride 100g	Hydrochloric acid 35-38% by volume, specific gravity 1.18 50mls	-	-0.45	436	As example 28a

SUBSTITUTE SHEET (RULE 26)

28e	Aluminium	Aluminium Chloride 300g molecular weight 241.43 Al content 26.98% by weight	Ammonium Chloride 150g	Hydrochloric acid 35-38% by volume, specific gravity 1.18 75mls	-	-0.98	466	As example 28a
29	Copper	Copper Sulphate 150g	Ammonium chloride 75g	Hydrochloric acid-concentrated variable	-	1-2	> 350	As example 1
30	Copper	Copper Sulphate 150g	Ammonium chloride 75g	Hydrochloric acid-concentrated variable	-	1-2	> 350	As example 26
31	Copper	Copper	Ammonium chloride 75g	Hydrochloric acid-concentrated variable	-	1-2	> 350	Sewage treatment - disinfectant for sewage solids
32	Copper	Copper Sulphate 150g	Ammonium Sulphate 75g	Sulphuric 98% variable	-	1-2	> 350	Food preservation fungicide spray for fruit and vegetables
33	Copper	Copper Sulphate 150g	Ammonium Sulphate 75g	Sulphuric 98% variable	-	1-2	> 350	Food preservation - meat disinfectant
34	Copper	Copper Sulphate 150g	Ammonium Sulphate 75g	Sulphuric 98% variable	Fructose	1-2	> 350	Flower, tree and shrub preservation e.g. Christmas trees - bactericide and fungicide
35	Copper	Copper Sulphate 150g	Ammonium Sulphate 75g	Sulphuric 98% variable	-	1-2	> 350	Food preservation seafood preservative
36	Copper	Copper Sulphate 150g	Ammonium Sulphate 75g	Sulphuric 98% variable	-	1-2	> 350	Food preservation - for fruit and vegetables

37	Copper	Copper sulphate 150g	Ammonium Chloride 75g	Hydrochloric acid-concentrated variable	-	1-2	> 350	Food preservation- food processing area sanitiser
38	Copper	Copper sulphate 300g	Ammonium sulphate 82.5g	Sulphuric 98% variable	-	1-2	> 350	Metal preservation - metal sealing, plating and anti-corrosion
39	Nickel	Nickel sulphate 300g	Ammonium sulphate 82.5g	Sulphuric 98% variable	-	1-2	> 350	As example 38
40	Nickel	Nickel sulphate 200g	Ammonium sulphate 75g	Sulphuric 98% variable	Zinc sulphate	1-2	> 350	Industrial-algaecide and bactericide particularly in cooling towers to inhibit legionella bacteria
41	Titanium	Titanium sulphate 300g	Ammonium sulphate 82.5g	Sulphuric 98% variable	-	1-2	> 350	As example 38
42	Vanadium	Vanadium sulphate 300g	Ammonium sulphate 82.5g	Sulphuric 98% variable	-	1-2	> 350	As example 38
43	Zinc	Zinc sulphate 150g	Ammonium phosphate 75g	Phosphoric acid variable	Citric Acid	1-2	> 350	Medical, for use in repairing impaired/damaged mitochondria e.g. in patients with AIDS presently taking more than one AIDS treatment drug.
44	Magnesium	Magnesium sulphate 150g	Ammonium phosphate 75g	Phosphoric acid variable	Malic Acid	1-2	> 350	Medical, for use in repairing impaired/damaged mitochondria e.g. in patients with AIDS presently taking more than one AIDS treatment drug.
45	Zinc	Zinc sulphate 150g	Ammonium phosphate 75g	Phosphoric acid variable	Citric acid And Pyruvic acid	1-2	> 350	Medical - for use in treating ME chronic fatigue Syndrome

46	Magnesium	Magnesium sulphate 150g	Ammonium phosphate 75g	Phosphoric Acid variable	Malic acid	1-2	> 350	Medical - for use in treating ME chronic fatigue syndrome
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* N.B. variable denotes amount adjusted to obtain required specific pH and mV values, low pH and high mV being preferred.

From these examples it will be appreciated that the compositions may include one or more other additional components, besides the metal such as the preferred mineral, metal ion modifier, acid and water. By way of example, in zinc mineral compositions for dietary supplements or medical use it is preferred to incorporate one or more of the water soluble vitamins C, B5 and B6, each of which appear to play a role in accelerating delivery of the zinc mineral to cells via the bloodstream, to enhance the beneficial zinc ion effects .

In the case of magnesium mineral compositions for treating or preventing viral infections, it is preferred to include vitamins B1 and B3 to promote or synergise such beneficial anti-viral properties of the magnesium ion.

In the case of magnesium mineral compositions for treating chronic fatigue syndrome, it is preferred to include malic acid because it is useful for the same purpose. Compositions based on magnesium for treating PMT (pre-menstrual tension) preferably also include a natural diuretic to relieve water retention and for such compositions intended to treat insomnia, it is preferred also to include known sleep enhancers such as valerian or rapid eye movement extenders such as melatonin.

Zinc mineral compositions intended for enhancing vitality and for countering the effects of tiredness may further contain one or more of the following or other stimulants: caffeine, nicotine and ginseng.

The present compositions when used as a mineral source for rapid ingestion can demonstrate the following properties and advantages:

- (1) An ability to bind metal ions, eg from salts through the action of at least one metal ion modifier within the acidic, electrolytically active aqueous solution. In this regard, the metal ion modifier appears to act as a binder and/or buffering agent which links up with the metal ions, and which 'buffers' those desirable metal ions against removal from the bloodstream.

- (2) An ability to deliver and retain those mineral metals in an ionically modified form in the human or animal bloodstream through the buccal muscosa, oesophagus or stomach rapidly, i.e within a few minutes.
- (3) The ionically modified mineral metal ions appear to remain in the blood serum to
5 facilitate bio-availability of the specific mineral metal for cellular uptake, and moreover certain effects which have been observed appear to indicate that it is not only the bio-availability which is enhanced, but also and quite surprisingly the bioactivity of the mineral. This could be due to the apparent stability of overall cationic charge of the ions incorporating the metal.
- 10 (4) The ionically modified mineral metal ions retain a net positive electrical charge which interacts with negatively charged virus, bacteria or fungal cells, forming a complex with these pathogens.
- (5) The ionically modified mineral metal ions in solution carry and appear to have the ability to deliver an electrical charge. This charge coupled with the overall mineral metal
15 delivery system and the selected mineral metals help to control pathogens (bacteria, fungi and virus) apparently by degrading their membranes, complexing the pathogens thereby rendering them inactive or otherwise unable to harm the host's body. In this regard the present mineral metal compositions when delivered into the bloodstream, help the body's natural immune system to fight infection.
- 20 (6) Substantially improved bio-availability of the mineral in the bloodstream after digestion or absorption in terms of mineral quantity and substantially reduced time for the mineral to become bio-available after digestion or absorption i.e. rapid absorption.
- (7) Additional medical benefits have surprisingly been found above and beyond the known benefits of mineral supplements. The present compositions have a wide variety
25 of uses in medicine as hereinbefore described and whilst such benefits have been shown applicable to the treatment of human disease, similar uses are proposed in the

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treatment of animals by way of using the present compositions as veterinary mineral supplements.

The present compositions may be formulated as aqueous solutions and presented for use and/or sale within dropper bottles for convenient addition to foodstuffs, beverages or to water for consumption. Alternatively the compositions can be applied directly to the buccal mucosa for even more rapid mineral metal absorption into the bloodstream.

Alternatively the compositions may be formulated as capsules containing a unit dose, or presented in tablet form after evaporating or freeze drying the compositions in such a manner that the pH and electrolytic potential can be substantially restored to the preferred values described herein by the presence of acid in the stomach.

In order that application of the invention may be demonstrated, reference is now made to the accompanying drawings and the following non-limiting examples.

Figure 1 shows the antibacterial activity of Example 24 against *Escherichia coli* QC strain at a variety of dilutions. Exposure was for one hour at 37 degrees centigrade. Under these testing conditions, a dilution of as little as 0.04 ppm was still effective in reducing bacterial counts by 99.9%. Recommended dosage is at the 1ppm level.

Actual Data:

Control: (0 ppm)	9×10^4 cfu/ml (colony forming units/millilitre)
1.0 ppm:	No recoverable bacteria
0.2 ppm:	No recoverable bacteria
0.04 ppm:	12.7 cfu/ml
0.008 ppm:	1×10^4 cfu/ml
0.0016 ppm:	6.4×10^5 cfu/ml

Figure 2 shows the results of treating a treatment plant effluent with a formulation according to Example 24, wherein the colony forming units plotted are of residual fecal coliforms. The conditions leading to these results were as follows:

1 hour Exposure Time, 22 Degrees Centigrade

	Typical Effluent Conditions, Mg / L:	
	Dissolved Oxygen	4.8
	COD	106
5	pH (max)	7.5
	pH (min)	7.1
	Ammonium (NH ₃ -N)	9.0
	Total N (Kjeldahl)	9.4
	Nitrogen Species (NO _x)	3.8
10	BOD	12

Figure 3 shows the antibacterial activity of an example 24 formulation against Escherichia coli QC strain at a 1ppm concentration. Exposure was for one hour at 37 degrees centigrade in 1 mM PO₄ buffer.

15 Actual Data:

Control: (0 ppm)	9 x 10 ⁴ cfu/ml
1ppm:	No recoverable bacteria

Further results against a variety of bacteria using a formulation corresponding to Example 24 are shown in figure 4. The conditions were broadly similar to those described with reference to Figure 3.

The figures demonstrate the bacteriocidal activity.

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CLAIMS

1. A metal-containing composition substantially comprising

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(i) at least one water soluble metal compound which forms metal ions when dissolved in water, which consists of compound of at least one of the following: zinc, magnesium, copper, selenium, iron, nickel, titanium, 10 vanadium, and aluminium,

(ii) at least one metal ion binding, complexing or sequestering agent other than chelate or glutamate,

15 (iii) at least one acid, and

(iv) water

said composition having a pH of less than 3 and an 20 electrolytic potential in excess of 50 millivolts.

2. A composition as claimed in claim 1 wherein said metal compound is a compound of one of the following mineral metals: copper, magnesium, selenium, iron and 25 zinc.

3. A composition as claimed in claim 1 or 2 which essentially consists of (i) - (iv) as defined in claim 1.

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4. A composition as claimed in any preceding claim which consists of (i) - (iv) as defined in claim 1 apart from any unavoidable impurities.

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5. A composition as claimed in any preceding claim wherein (i) is an inorganic salt of zinc, magnesium, copper, selenium, iron, nickel, titanium or vanadium.

10 6. A composition as claimed in claim 5 in which said salt (i) is sulphate, chloride or nitrate.

7. A composition as claimed in claim 5 or 6 in which said salt (i) is a zinc, magnesium, copper, iron or
15 selenium salt.

8. A composition as claimed in claim 7 in which (i) is zinc sulphate, magnesium sulphate, iron sulphate or copper sulphate.

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9. A composition as claimed in any preceding claim wherein (ii) comprises one or more inorganic ammonium compounds capable of dissociating in water into ammonium ions such as one or more of ammonium sulphate, ammonium
25 chloride, ammonium phosphate, and ammonium citrate.

10. A composition as claimed in claim 9 wherein (ii) is ammonium sulphate.

11. A composition as claimed in any preceding claim in which (iii) comprises one or more of sulphuric, hydrochloric, phosphoric and citric acids.

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12. A composition as claimed in claim 11 wherein (iii) is concentrated sulphuric or hydrochloric acid.

13. A composition as claimed in any preceding claim in which (iv) consists essentially of distilled water or entirely of distilled water apart from any unavoidable impurities.

14. A composition as claimed in any preceding claim in which the pH value is less than 2.5.

15. A composition as claimed in claim 14 in which the pH value is 2 or less such as in the range of 1 to 2.

16. A composition as claimed in any preceding claim in which the electrolytic potential is in excess of 100 millivolts.

17. A composition as claimed in claim 16 which the electrolytic potential is in excess of 200 millivolts.

18. A composition as claimed in claim 17 in which the electrolytic potential is in excess of 300 millivolts and

preferably at least 340 millivolts.

19. A composition as claimed in claim 18 in which the electrolytic potential is in the range of 340 to 400 5 millivolts.

20. A method of making a composition as claimed in any preceding claim comprising dissolving (i) in distilled water, adding (ii) and mixing or allowing to dissolve, 10 then adding (iii) whilst simultaneously monitoring the pH and electrolytic potential of the composition until a required value of each measurement is obtained.

21. A method as claimed in claim 20 in which (i) is as 15 defined in any one of claims 5 to 8.

22. A method as claimed in claim 20 or 21 in which (ii) is as defined in claim 9 or 10.

20 23. A method as claimed in any one of claims 20 to 22 wherein (iii) is as defined in claim 11 or 12.

24. An antimicrobial, antiviral, antiretrovirus or antifungal formulation comprising a composition as claimed 25 in any one of claims 1 to 19 in conjunction with a pharmaceutically acceptable carrier, diluent or excipient therefor.

25. Use of a composition as claimed in any one of claims 1 to 19 for the treatment of water, or predominantly water - containing material.

5 26. Use of a composition as claimed in any one of claims 1 to 19 for the treatment of sewage, industrial or municipal wastes.

27. Use of a composition as claimed in any one of claims 10 1 to 19 for the treatment of foodstuffs as a disinfectant or bactericide, particularly copper containing such compositions.

28. Use of a composition as claimed in any one of claims 15 1 to 19 for the preservation of plants, flowers, trees or shrubs.

29. Use of a composition as claimed in any one of claims 1 to 19 in the treatment of a metal for coating, sealing, 20 plating or otherwise forming an anti-corrosive layer upon a metallic substrate.

30. Use as claimed in claim 29 wherein the composition contains one or more of copper, nickel, titanium or 25 vanadium.

31. A composition as claimed in any one of claims 1 to 19 for use as a medicament for treating or preventing a

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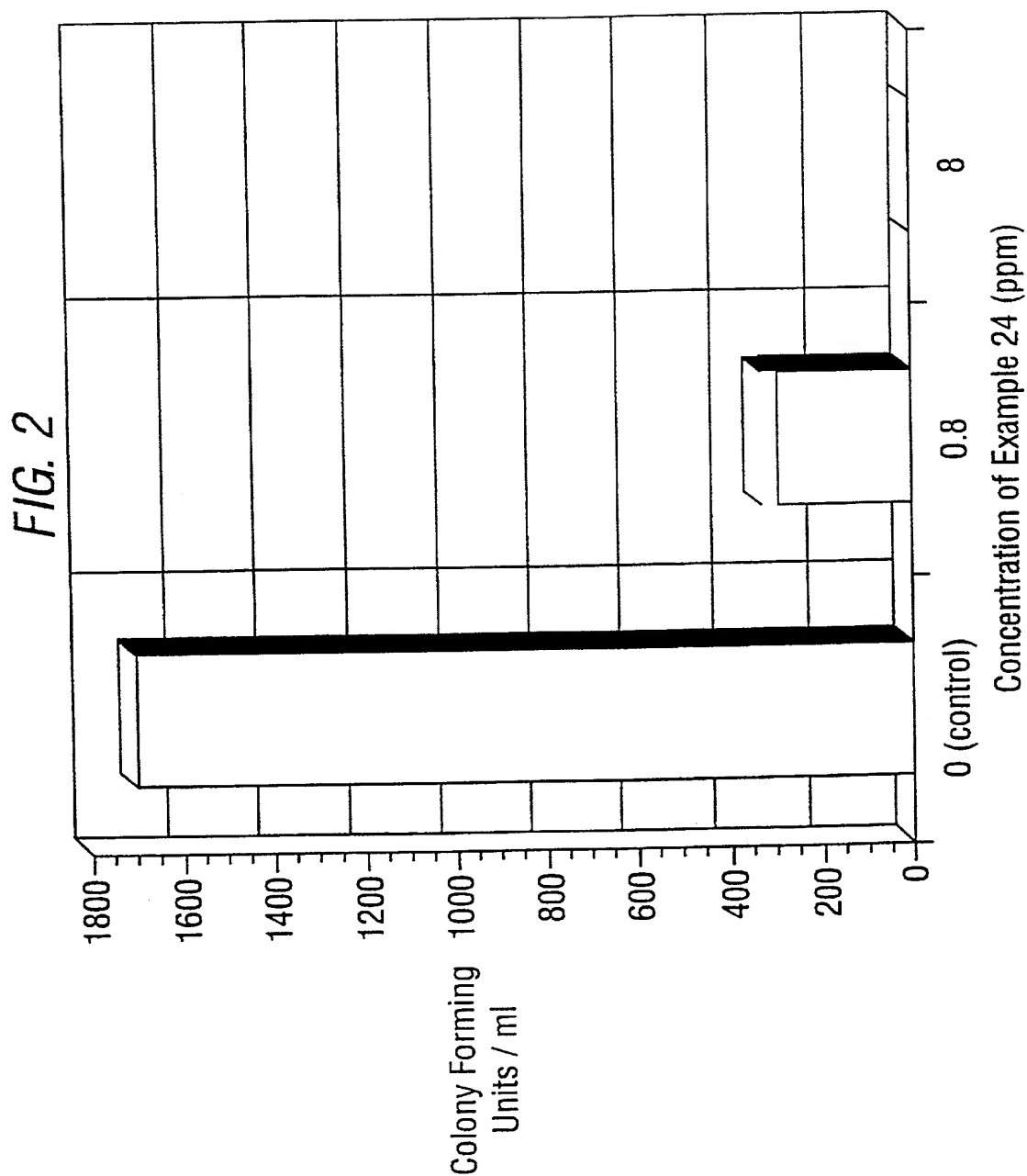
pathogenic disease or disorder.

32. Use of a composition as claimed in any one of claims 1 to 19 in the preparation of a medicament for treating or preventing a pathogenic disease or disorder.

33. Use of a composition as claimed in any one of claims 1 to 19 as an antimicrobial, antiviral, anti-retrovirus, or antifungal formulation.

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FIG. 3

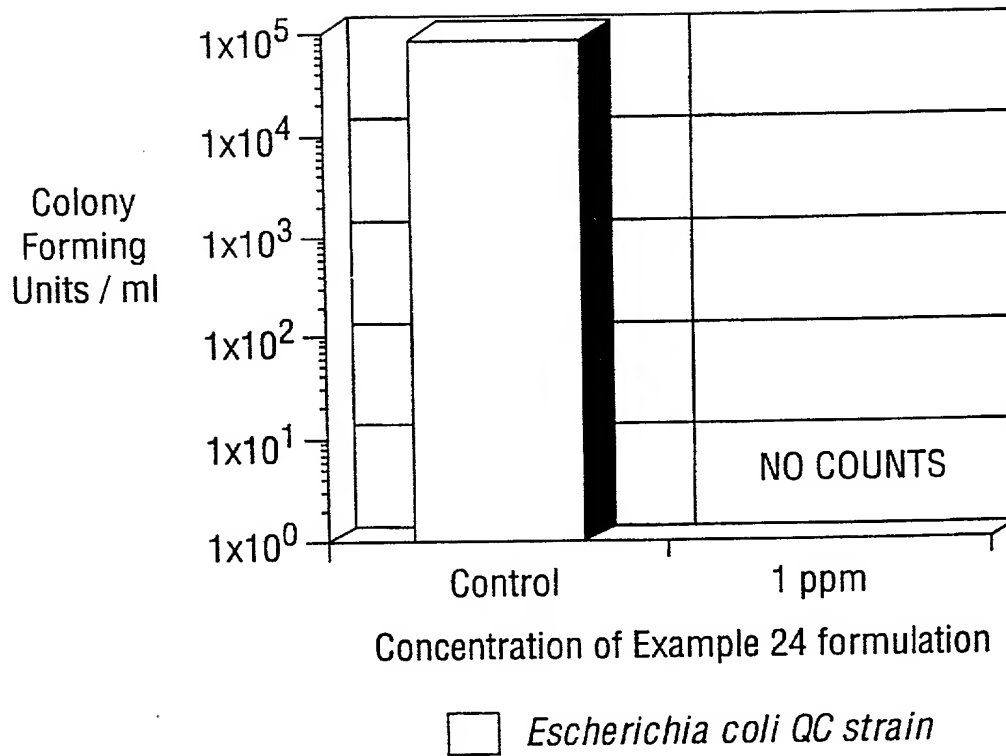
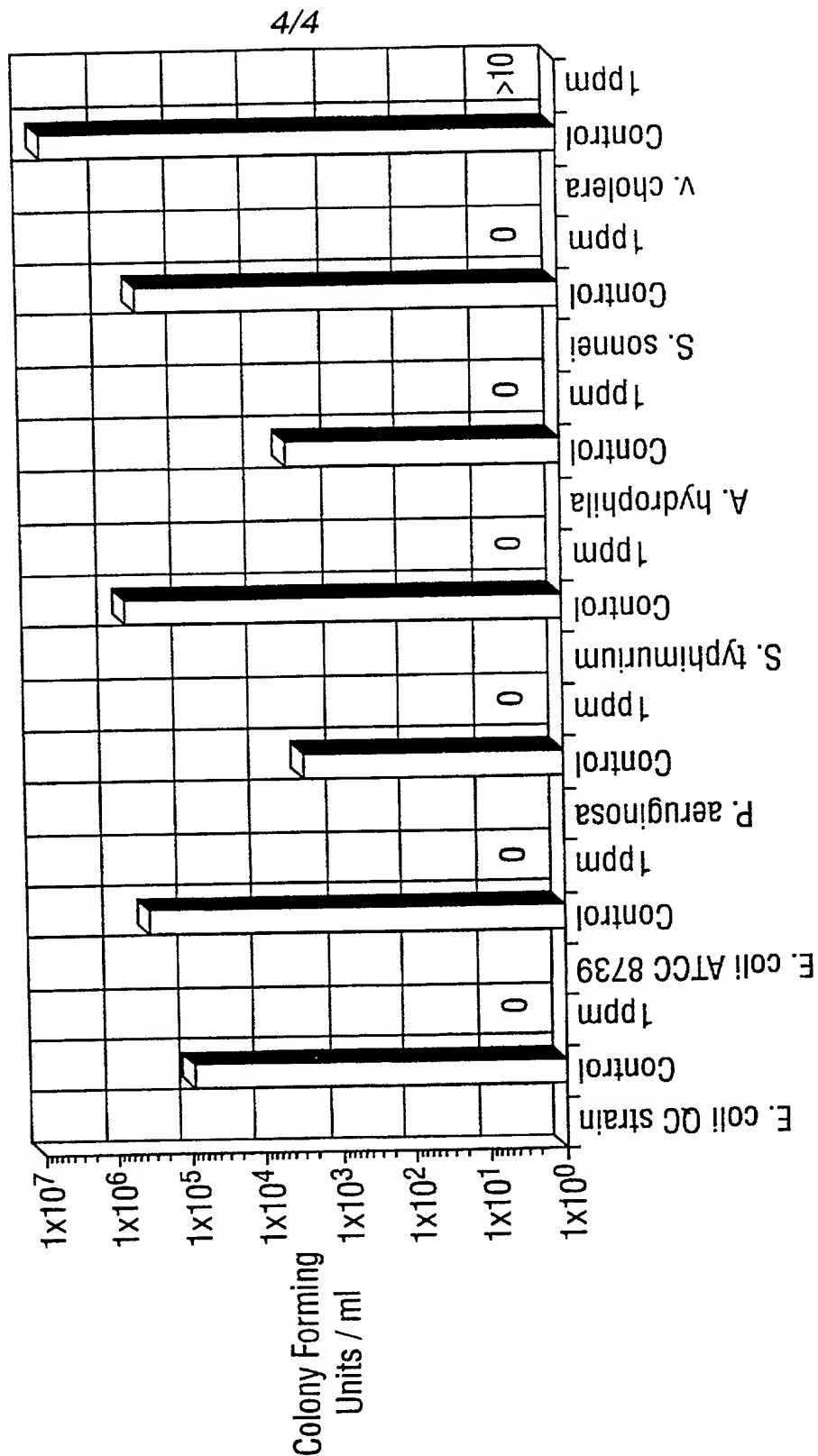


FIG. 4



Attorney Docket No.: MAG 2 0003

DECLARATION AND POWER OF ATTORNEY FOR PATENT APPLICATION

As a below inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name,

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

METAL-CONTAINING COMPOSITIONS, PREPARATIONS AND USES

the specification of which:

☐ is attached hereto

☐ was filed on _____
as Application Serial No. _____
and was amended on _____
(if applicable)

☐ was filed as International Application No. PCT/GB00/03364 on 31 August 2000.

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, § 1.56 (a).

I hereby claim foreign priority benefits under Title 35, United States Code, § 119 or 365(b) of any foreign application(s) for patent or inventor's certificate, or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed above and have also identified below, by check the box, any foreign application(s) for patent or inventor's certificate, or of any PCT international application having a filing date before that of the application on which priority is claimed:

Prior Foreign Applications

<u>9920539.5</u> (Number)	<u>Great Britain</u> (Country)	<u>31 August 1999</u> (Day/Month/Year Filed)	<u>No</u> Certified Copy Attached?
<u>9928337.6</u> (Number)	<u>Great Britain</u> (Country)	<u>30 November 1999</u> (Day/Month/Year Filed)	<u>No</u> Certified Copy Attached?

I hereby claim the benefit under 35 U.S.C. 119(e) of an United States provisional application(s) listed below.

Application No(s)	(Day/Month/Year Filed)	<input type="checkbox"/> additional provisional application numbers are listed on a supplemental priority data sheet attached
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I hereby claim the benefit under Title 35, United States, § 120 of any United States application(s) or any PCT international application designating the United States of America, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application or PCT International application in the manner provided by the first paragraph of Title 35, United States Code, § 112, I acknowledge the duty to disclose material information which is material to patentability as defined in Title 37, of Federal Regulations Code, § 1.56(a) which became available between the filing date of the prior application and the national or PCT international filing date of this application:

U.S. Parent Application
or PCT Parent Number

Parent Filing Date
(MM/DD/YYYY)

Parent Patent Number
(if Applicable)

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POWER OF ATTORNEY: As a named inventor, I hereby appoint the following attorneys to prosecute this application and transact all business in the Patent and Trademark Office connected therewith.

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both under § 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

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